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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/18/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,186

Applicant(s)

YOSHII ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 021302.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's election of DNA biopolymers species in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's remarks regarding examination of the protein biopolymer species is acknowledged. The issue will be addressed when claims drawn to the elected species are deemed allowable.

Amendments adding new claims 9-22 filed in Paper No. 6 is acknowledged.

Claims 1-22 are currently pending.

Information Disclosure Statement

2. The references listed on the 1449 received 31 January 2001 have been reviewed and considered. Additionally, the International Search Report for PCT/JP99/04459 has been reviewed.

Claim Objections

3. Claim 8 is objected to because of the following informalities:

- a. In Claim 8, line 4, "and" is improperly recited. The "and" should be deleted.
- b. In Claim 8, line 8, a comma (,) improperly follows "spot locations". The comma should be replaced by a semi-colon.

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Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-6 and 9-19 are indefinite in Claim 1 for the recitation "capable of being spotted" because it is unclear whether the surface is spotted or is in a condition to be spotted at some future time. Therefore, it is unclear what structural components of the biochip are being claimed. It is suggested that Claim 1 be amended to define the structural components of the biochip e.g. delete "capable of being" (specification, page 3, first and second paragraphs).

b. Claims 3 and 4 are indefinite for the recitation "wherein a member provided with the surface" because it is unclear how the "member" is "provided" and because it is unclear how or whether the "member" structurally relates to the surface and storage medium. Therefore, it is unclear what structural components of the biochip are being claimed. It is suggested that Claims 3 and 4 be amended to define the structural components of the biochip e.g. delete "a member provided with" and at the end of the claim, insert "from a case member" (page 7, first full paragraph).

c. Claim 6 is indefinite for the recitation "information of spot locations on the biochip surface in relation to information of the type of biopolymers" because "in relation to" is a non-specific relational phrase and therefore it is unclear how the spot information relates to the

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type of biopolymer information. It is suggested that Claim 6 be amended to define the relationship e.g. replace "in relation to" with "to provide" (page 4, last paragraph).

d. Claims 7 and dependent claims 20-22 provides for the use of a biochip, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It is suggested that Claims 7 and 20-22 be amended to recite method step for using the biochip e.g. contacting the biochip with a sample, hybridizing the sample, detecting fluorescence, searching database information, displaying database search results (page 4, last paragraph).

e. Claims 8 and 20-22 indefinite in Claim 8 for the recitation "information of spot locations on the biochip surface in relation to information of the type of biopolymers" because "in relation to" is a non-specific relational phrase and therefore it is unclear how the spot information relates to the type of biopolymer information. It is suggested that Claim 8 be amended to define the relationship e.g. replace "in relation to" with "to provide" (page 4, last paragraph).

f. Claims 8 and 20-22 are indefinite in Claim 8 for the recitation "the data stored" because the recitation lacks proper antecedent basis in the preceding steps of the claim. It is suggested that Claim 8 be amended to provide proper antecedent basis e.g. replace "data" with "information".

g. Claim 9 is indefinite for the recitation "the location, the type or the amount" because the recitation lacks proper antecedent basis in Claim 9. It is suggested that Claim 9 be amended to provide proper antecedent basis e.g. replace each "the" with "a".

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Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

7. Claims 7 and dependent claims 20-22 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-4, 6-9, 13, 14, 17-19, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Perttunen et al (U.S. Patent No. 5,968,728, filed 30 April 1997).

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Regarding Claim 1, Perttunen et al disclose a biochip comprising a surface capable of being spotted with a plurality of biopolymers in a predetermined pattern i.e. a first member having a plurality of sites (Column 7, lines 41-47) and a storage medium for storing information of the biopolymers to be spotted i.e. second member (Column 7, lines 55-58 and Fig. 11 and 12).

Regarding Claim 2, Perttunen et al disclose a biochip comprising a surface spotted with a plurality of biopolymers in a predetermined pattern i.e. a first member having a plurality of oligonucleotides at each site (Column 7, lines 41-47, Column 8, lines 20-34 and Fig. 11) and a storage medium for storing information of the biopolymers to be spotted i.e. second member (Column 7, lines 55-58).

Regarding Claim 3, Perttunen et al disclose the biochip wherein a member (i.e. package) provided with the surface and the storage medium are detachable (Column 7, lines 48-54 and Fig. 12).

Regarding Claim 4, Perttunen et al disclose the biochip wherein a member provided with the surface and the storage medium are formed integrally i.e. formed of a unitary member (Column 7, lines 48-54).

Regarding Claim 6, Perttunen et al disclose the biochip wherein the storage medium stores information of spot locations on the surface and

Regarding Claim 7, Perttunen et al disclose a method for using a biochip wherein a plurality of biopolymers are spotted on a surface of the biochip in a predetermined pattern, the biochip comprising a storage medium and information of the spot locations are written to the storage medium in relation to information of the type of biopolymer spotted on each spot (Column 7, lines 39-67 and Column 8, lines 20-54).

Regarding Claim 8, Perttunen et al disclose a method of using a biochip comprising applying a sample to the biochip wherein the biochip comprises a surface spotted with a plurality of biopolymers in a predetermined pattern (Column 7, lines 55-58); detecting a spot

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location where the sample has bound wherein the biochip comprises a storage medium that stores information of spot locations in relation to information of spotted biopolymers; and storing a displaying information of the biopolymer that has bound with a sample by searching the data stored in the storage medium based on the spot location bound with sample molecule (Column 8, lines 20-54).

Regarding Claim 9, Perttunen et al disclose the biochip wherein the information stored in the storage medium comprises the location and type of biopolymer (Column 7, lines 55-58).

Regarding Claim 13, Perttunen et al disclose the biochip further comprising a semiconductor memory support (Column 4, lines 42-47 and 62-65).

Regarding Claim 14, Perttunen et al disclose the semiconductor memory chip comprises silicon (Column 4, lines 42-47).

Regarding Claim 17, Perttunen et al disclose the semiconductor memory support is the surface spotted with the biopolymer (Column 4, lines 42-51).

Regarding Claim 18, Perttunen et al disclose the biochip wherein the biopolymer comprises DNA (Column 1, lines 36-45).

Regarding Claim 19, Perttunen et al disclose the biochip wherein the biopolymer comprises a protein (Column 4, lines 24-26).

Regarding Claim 21, Perttunen et al disclose the method of Claims 7 and 8 wherein the biopolymer comprises DNA (Column 1, lines 36-45).

Regarding Claim 22, Perttunen et al disclose the method of Claims 7 and 8 wherein the biopolymer comprises a protein (Column 4, lines 24-26).

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10. Claims 1-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Nova et al (U.S. Patent No. 6,284,459 B1, filed 5 September 1996).

Regarding Claim 1, Nova et al disclose a biochip comprising a surface capable of being spotted with a plurality of biopolymers in a predetermined pattern i.e. matrix and a storage medium for storing information of the biopolymers to be spotted i.e. memory (Column 7, lines 6-65 and Fig. 22-30).

Regarding Claim 2, Nova et al disclose a biochip comprising a surface spotted with a plurality of biopolymers in a predetermined pattern i.e. matrix and a storage medium for storing information of the biopolymers to be spotted i.e. memory (Column 7, lines 6-65 and Fig. 22-30) wherein the biopolymers are spotted into each location (Column 19, lines 46-51).

Regarding Claim 3, Nova et al disclose the biochip wherein a member provided with the surface and the storage medium are detachable i.e. the memory and matrix are pressed to fit into the well (Column 41, line 55-Column 42, line 8 and Fig. 22-30).

Regarding Claim 4, Nova et al disclose the biochip wherein a member provided with the surface and the storage medium are formed integrally i.e. the memory and matrix are bonded into the well (Column 41, line 55-Column 42, line 8 and Fig. 22-30).

Regarding Claim 5, Nova et al disclose the biochip wherein the storage medium comprises a semiconductor memory which can read/write information in a non-contact state (Column 57, lines 28-58).

Regarding Claim 6, Nova et al disclose the biochip wherein the storage medium stores information of spot locations on the surface in relation to the type of biopolymers spotted on each spot i.e. provides identifying information for each biomolecules (Column 8, lines 42-47).

Regarding Claim 7, Nova et al disclose a method for using a biochip wherein a plurality of biopolymers are spotted on a surface of the biochip in a predetermined pattern, the biochip comprising a storage medium and information of the spot locations are written to the storage

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medium in relation to information of the type of biopolymer spotted on each spot (Column 14, lines 47-65).

Regarding Claim 8, Nova et al disclose a method of using a biochip comprising applying a sample to the biochip wherein the biochip comprises a surface spotted with a plurality of biopolymers in a predetermined pattern; detecting a spot location where the sample has bound wherein the biochip comprises a storage medium that stores information of spot locations in relation to information of spotted biopolymers; and storing a displaying information of the biopolymer that has bound with a sample by searching the data stored in the storage medium based on the spot location bound with sample molecule (Column 14, lines 47-65).

Regarding Claim 9, Nova et al disclose the biochip wherein the information stored in the storage medium comprises the location, type and amount of biopolymer (Column 14, lines 54-60).

Regarding Claim 10, Nova et al disclose the biochip wherein the storage medium further comprises a covered surface (Column 31, lines 40-45 and Column 32, lines 22-38).

Regarding Claim 11, Nova et al disclose the covered surface comprises a plastic or glass (Column 31, lines 40-45 and Column 32, lines 22-38).

Regarding Claim 12, Nova et al disclose the covered surface protects the storage medium for exposure to a solution (Column 32, lines 22-27).

Regarding Claim 13, Nova et al disclose the biochip further comprising a semiconductor memory support (Column 50, lines 34-45).

Regarding Claim 14, Nova et al disclose the biochip wherein the semiconductor memory support comprises a silicon wafer i.e. chip (Column 19, lines 63-67).

Regarding Claim 15, Nova et al disclose the semiconductor memory support is covered (Column 32, lines 22-38).

Regarding Claim 16, Nova et al disclose the semiconductor memory support is covered with a resin i.e. agarose (Column 32, lines 32-38).

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Regarding Claim 17, Nova et al disclose the semiconductor memory support is the surface spotted with the biopolymer (Column 8, lines 58-62 and Column 19, lines 63-67).

Regarding Claim 18, Nova et al disclose the biochip wherein the biopolymer comprises DNA (Column 24, lines 8-19).

Regarding Claim 19, Nova et al disclose the biochip wherein the biopolymer comprises a protein (Column 24, lines 8-19).

Regarding Claim 20, Nova et al disclose the biochip wherein the information stored in the storage medium comprises the amount of biopolymer (Column 14, lines 54-60).

Regarding Claim 21, Nova et al disclose the method of Claims 7 and 8 wherein the biopolymer comprises DNA (Column 24, lines 8-19).

Regarding Claim 22, Nova et al disclose the method of Claims 7 and 8 wherein the biopolymer comprises a protein (Column 24, lines 8-19).

11. Claims 1, 2 and 5-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Zeleny et al (U.S. Patent No. 6,215,894 B1).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Regarding Claim 1, Zeleny et al disclose a biochip comprising a surface capable of being spotted with a plurality of biopolymers in a predetermined pattern i.e. array and a storage medium for storing information of the biopolymers to be spotted i.e. barcode (Column 2, line 66-Column 3, line 7 and Fig. 1-2).

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Regarding Claim 2, Zeleny et al disclose a biochip comprising a surface spotted with a plurality of biopolymers in a predetermined pattern i.e. array and a storage medium for storing information of the biopolymers to be spotted i.e. barcode (Column 2, line 66-Column 3, line 7 and Fig. 1-2).

Regarding Claim 5, Zeleny et al disclose the biochip wherein the storage medium comprises a semiconductor memory which can read/write information in a non-contact state (Column 3, lines 25-30).

Regarding Claim 6, Zeleny et al disclose the biochip wherein the storage medium stores information of spot locations on the surface in relation to the type of biopolymers spotted on each spot i.e. provides identifying information for each biomolecules (Column 2, lines 20-32).

Regarding Claim 7, Zeleny et al disclose a method for using a biochip wherein a plurality of biopolymers are spotted on a surface of the biochip in a predetermined pattern, the biochip comprising a storage medium and information of the spot locations are written to the storage medium in relation to information of the type of biopolymer spotted on each spot (Column 2, line 66-Column 3, line 7 and Fig. 1-2).

Regarding Claim 8, Zeleny et al disclose a method of using a biochip comprising applying a sample to the biochip wherein the biochip comprises a surface spotted with a plurality of biopolymers in a predetermined pattern; detecting a spot location where the sample has bound wherein the biochip comprises a storage medium that stores information of spot locations in relation to information of spotted biopolymers; and storing a displaying information of the biopolymer that has bound with a sample by searching the data stored in the storage medium based on the spot location bound with sample molecule (Column 2, lines 13-32).

Regarding Claim 9, Zeleny et al disclose the biochip wherein the information stored in the storage medium comprises the location, type and amount of biopolymer (Column 2, lines 20-32).

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Conclusion

12. No claim is allowed.

13. The examiner for this application has changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
April 15, 2002